

K122984

Atlas Gold PTA Dilatation Catheter

**510(k) Summary
21 CFR 807.92**

OCT 22 2012

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (l)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter Information:

Applicant: Bard Peripheral Vascular, Inc
1625 West 3rd Street
Tempe, Arizona 85281

Phone: 480-303-2752

Fax: 480-449-2546

Contact: Jennifer Logvin, Senior Regulatory Affairs Specialist

Date: July 20, 2012

Subject Device Name:

Device Trade Name: **Atlas Gold PTA Dilatation Catheter**

Common or Usual Name: Percutaneous Catheter (21 CFR 870.1250,
Product Code DQY, LIT)

Classification: Class II

Classification Panel: Cardiovascular

Predicate Device:

- Atlas[®] PTA Balloon Dilatation Catheter (K120971, cleared April 19, 2012)

Device Description:

The Atlas Gold PTA Dilatation Catheter is balloon catheter consisting of an over the wire catheter with a balloon fixed at the distal tip. The proprietary non-compliant, low profile balloon is designed to provide consistent balloon diameters and lengths even at high pressures. Two radiopaque markers delineate the working length of the balloon and aid in balloon placement. The coaxial catheter includes an atraumatic tip to facilitate advancement of the catheter to and through the stenosis. The over the wire catheter is compatible with 0.035" guidewire and is available in 80 and 120 cm working lengths. The proximal portion of the catheter includes a female luer lock hub connected to the inflation lumen, and a female luer-lock hub connected to the guidewire lumen.

Packaged with every product is a profile reducing sheath that is positioned over the balloon for protection before use. A re-wrapping tool is also provided on the catheter shaft. This product is not manufactured with any latex.

Attribute	Atlas Gold PTA Dilatation Catheter Product Offering
Balloon Diameter (mm)	12, 14, 16, 18, 20, 22, 24, 26
Balloon Length (cm)	2, 4, 6
Catheter Shaft Lengths (cm)	80, 120
Introducer Sheath Compatibility	7F: 12 2,4,6 14 2,4
Compatible Balloon Diameters and Lengths (mm x cm)	8F: 14 6 16 2,4,6 18 2,4
	9F: 18 6 20 2,4
	10F: 22 2,4 24 2,4
	12F: 26 2,4

Indications for Use of Device:

The Atlas Gold PTA Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the iliac arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of stents and stent grafts in the peripheral vasculature. This catheter is not for use in coronary arteries.

Comparison of Indications for Use to Predicate Device:

The indication for use statement for the Atlas Gold PTA Dilatation Catheter is identical to that of the predicate device, the Atlas PTA Balloon Dilatation Catheter.

Technological Comparison to Predicate Device:

The Atlas Gold PTA Dilatation Catheter has the following similarities to the predicate device:

- Same intended use
- Same indications for use
- Same target population
- Same fundamental scientific technology
- Same operating principle
- Similar packaging materials and configuration
- Same sterility assurance level and method of sterilization

Performance Data:

To demonstrate substantial equivalence of the subject device, the Atlas Gold PTA Dilatation Catheter to the predicate device, the technological characteristics and performance criterion were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Assessment procedures, the following *in vitro* tests were performed on the subject device:

- Dimensional Verification
 - Tip Length
 - Balloon Outer Diameter
 - Balloon Working Length

- Catheter Shaft Outer Diameter
 - Catheter Shaft Inner Diameter
 - Catheter Shaft Length
- Media Interaction
- Equipment Interface
- Sheath Compatibility
- Rated Burst Pressure
- Balloon Burst Mode
- Catheter Shaft Leaks
- Catheter Shaft Burst
- Fatigue
- Balloon Nominal Pressure
- Balloon Distensibility
- Inflation Time
- Deflation Time
- Balloon to Shaft Tensile
- Catheter Shaft Elongation
- Hub to Shaft Tensile
- Tip Tensile
- Tip Morphology
- Trackability (Flexibility and Kink)
- Tip Visibility
- Catheter Shaft Visibility
- Marker Band Visibility
- Marker Band Alignment
- Balloon Burst Strength in a Stent/Stent Graft
- Fatigue in a Stent/Stent Graft
- Balloon Removal from a Stent/Stent Graft
- Visual Inspection of Packaging
- Dye Penetration
- Pouch Tensile Strength

The results from these tests demonstrate that the technological characteristics and performance criteria of the Atlas Gold PTA Dilatation Catheter is comparable to the predicate device and that it can perform in a manner equivalent to devices currently on the market for the similar intended use.

Biocompatibility:

To demonstrate substantial equivalence of the subject device, the Atlas Gold PTA Dilatation Catheter to the predicate device, the following biocompatibility testing was performed in accordance ISO 10993-1:2009, "Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process," and "Blue Book Memorandum – G95-1 Use of International Standard ISO 10993: Biological Evaluation of Medical Devices Part 1: Evaluation and Testing."

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Hemocompatibility
 - Hemolysis, In Vivo Thrombogenicity, Complement Activation
- Material Mediated Pyrogenicity

The results from these tests demonstrate that the subject device, the Atlas Gold PTA Dilatation Catheter, is comparable to the predicate device and that it is considered safe and biocompatible for its intended use.

Conclusions:

The subject device, the Atlas Gold PTA Dilatation Catheter, met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The Atlas Gold PTA Dilatation Catheter is substantially equivalent to the legally marketed predicate device, the Atlas PTA Balloon Dilatation Catheter.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

OCT 22 2012

Bard Peripheral Vascular, Inc.
C/O Mr. Mark Job
Regulatory Technical Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K122984

Trade/Device Name: Atlas GOLD PTA Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: September 25, 2012
Received: September 26, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

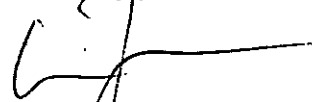
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Atlas Gold PTA Dilatation Catheter

Indications for Use: The Atlas Gold PTA Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the iliac arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of stents and stent grafts in the peripheral vasculature. This catheter is not for use in coronary arteries.


Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K122984